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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,893	01/17/2001	Shih-Chieh Hung	11709-003001	6011

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EXAMINER

GARVEY, TARA L

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/761,893

Applicant(s)

HUNG ET AL.

Examiner

Tara L Garvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5/27/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-11 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11 and 21-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2003 has been entered.

Claims 1-7, 9-11 and 21-31 were considered in the Final Office Action mailed July 28, 2002. Claims 8 and 12-20 were cancelled. Claims 1, 5, 7, 22 and 25 were amended in the May 27, 2003 paper. Claims 1-7, 9-11 and 21-31 are pending and are under consideration.

### ***Response to Amendment***

#### **Claim Rejections - 35 USC § 112**

The rejection of claims 1-7, 9-11 and 21-31 under 35 U.S.C. §112, second paragraph, as being indefinite has been withdrawn in view of the Applicants' amendment.

#### **Claim Rejections - 35 USC § 102**

The rejection of claims 1, 4, 5, 7, 9 and 10 under 25 U.S.C. §102(b) as being anticipated by Lucas et al (Wound Repair and Regeneration (1995) 3:449-460 has been withdrawn in view of the Applicants' amendment.

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The rejection of claims 1-5, 7, 9, 21, 22, 25 and 27 as being anticipated by Rieser et al (WO 97/46665; USP 6,242,247 is the national stage equivalent to WO 97/46665 and is reference in the following as it is in English) has been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 4, 5, 7, 9 and 10 under 25 U.S.C. §103(a) as being unpatentable over Lucas et al in view of Bruder et al (USP 5,942,225) has been withdrawn in view of the Applicants' amendment.

The rejection of claims 1-7, 9, 11, 21, 22, 24-27, 29 and 30 under 25 U.S.C. §103(a) as being unpatentable over Rieser et al in view of Bruder et al (USP 5,942,225) has been withdrawn in view of the Applicants' amendment.

New grounds of rejection, necessitated by Applicants' amendment, are presented below.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11 and 21-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a rejection for new matter. This is a new rejection necessitated by applicants' amendment of claims in Paper No. 17.

Claims 1-7, 9-11 and 21-31 are drawn to a method for isolating mesenchymal stem cells from a mixture of cells using a culture device. The mesenchymal stem cells are isolated from the culture device in which they were placed prior to the adherence of cells to this device.

The specification describes a method of isolating mesenchymal stem cells from bone marrow cells seeded in the upper plate of a culture device which contains pores through which smaller hematopoietic cells will pass. Non-adherent cells will be removed and other cells will adhere to the lower and the upper plates. The cells adhering to the upper plate maintain the ability of renewal and differentiation into mesenchymal tissue. The adherent cells from the upper plate will be recovered by trypsinizing and re-plating into a new dish while maintaining the ability to adhere. These cells from the upper plate are the isolated mesenchymal stem cells that can be maintained in 10% FBS supplemented DMEM-LG without differentiation.

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The specification does not describe a method of isolating the mesenchymal stem cells from the mixture of cells prior to adherence to the culture device. Thus, the newly added limitation to claim 1 constitutes new matter.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Caplan et al (USP 5,837,539, see column 18, lines 47-67 and example 6 in columns 46-48). The claims are drawn to a method of isolating mesenchymal stem cells from a mixture of cells using a culture device and isolating the cells prior to adherence to the culture device. Caplan et al teaches the use of monoclonal antibodies to separate mesenchymal stem cells from bone marrow aspirates. The cell mixture is placed in a centrifuge tube and then incubated with monoclonal antibodies attached to magnetic beads specific for the mesenchymal stem cells. The cells are separated based on their ability to bind to these antibodies and are then recovered from the beads. The "culture device" is not defined in the specification and thus would encompass a centrifuge tube.

***Conclusion***

Claims 1-7, 9-11 and 21-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tara L Garvey  
Examiner  
Art Unit 1636

TLG

  
JAMES KETTER  
PRIMARY EXAMINER